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Authentication of a copy of documents relating to patent application
No. UD2002A000173 for an industrial invention

We hereby declare that the attached copy conforms to the original documents
submitted with the foregoing patent application, the data of which are shown
in the enclosed official record.

Rome, the 09th June 2003

MANAGER
(Mr. Di Carlo)

**TO THE MINISTRY OF INDUSTRY, TRADE AND HANDICRAFTS
 ITALIAN PATENTS AND TRADEMARKS OFFICE - ROME
 APPLICATION FOR A PATENT FOR AN INDUSTRIAL INVENTION,
 FILING OF RESERVATIONS, EARLY ACCESS TO THE PUBLIC**

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 (Prov): UD

C. ELECTED DOMICILE: name:: /

Road: / City / Pt. Code / (Prov.) /

D. TITLE

Proposed class (section/class/subclass): A61F

Group/subgroup: 002/036

"FEMORAL PROSTHESIS FOR HIP ARTICULATION"

early access to the public: NO

if requested: date _____ protocol n. _____

E. INVENTOR'S NAME:

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1) LUALDI Gabriele

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Surname/name

3) _____

4) _____

F. PRIORITY:

Country or Organisation	Type	Number	Date
1) _____	_____	_____	_____
2) _____	_____	_____	_____

Enclosed: Y/N

Lifting of reservations: date _____ protocol n. _____

G. CENTRE OF COLLECTION OF CULTURES, EQUIPPED FOR MICROBIOLOGICAL METHODS, denomination:

H. SPECIAL REMARKS: _____

ATTACHED DOCUMENTS

Doc. 1) No. 2 PROV. No. pages 2'1 Abstract with the main drawing, description and claims (1 copy obligatory)

Doc. 2) No. 2 PROV. No. table 01 drawing (obligatory if indicated in the description, 1 copy)

Doc. 3) No. 1 RES Power of attorney, proxy or reference to general proxy

Doc. 4) No. 1 RES Designated inventor

Doc. 5) No. 0 RES Priority documents with Italian translation

Doc. 6) No. 0 RES Authorization or Deed of Assignment

Doc. 7) Full name of applicant

Lifting of reservations: date _____ protocol n. _____

compare single priority: _____

8) Certificate of payment of € 291,80 obligatory (fees paid for three years)

DOCUMENT COMPLETED ON: 02/08/2002

APPLICANT'S SIGNATURE:

LIGI STEFANO

(GLP N2-3348)

CONTINUATION PAGE YES/NO: NO

Authenticated copy of this document required YES/NO: YES

PROVINCIAL OFFICE OF INDUSTRY, TRADE AND HANDICRAFTS OF THE
CHAMBER OF COMMERCE OF UDINE

Code No: 30

FILING CERTIFICATE:

APPLICATION NO: UD2002A000173 Register A

This 05th day of the month of August in the year 2002

The above applicant has submitted to me the undersigned this application consisting of no additional sheet for the grant of the above patent registration.

L. VARIOUS NOTES OF THE ISSUING OFFICER: NIL

THE APPOINTED AGENT

ISSUING OFFICER

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Stamped: PROVINCIAL OFFICE OF INDUSTRY, TRADE AND HANDICRAFTS OF
UDINE

ABSTRACT OF INVENTION WITH MAIN DRAWING

APPLICATION N. UD2002A000173 REG.A FILING DATE 05/08/2002

PATENT NUMBER

ISSUING DATE

A. APPLICANT(S)

5 Denomination LIMA LTO S.p.A.

Residence Villanova di S. Daniele del Friuli (UD)

D. TITLE

FEMORAL PROSTHESIS FOR HIP ARTICULATION

(glp N2-3348)

10 Class proposed (section/class/subclass) A61F (group/subgroup) 002 036

L. ABSTRACT

Femoral prosthesis for the articulation of a femur (11) in a corresponding acetabular seating (13) of a hip, and comprising at least a femoral head (12) of a hemispherical shape, which is inserted into the acetabular seating (13), and pin means (18) which are engaged and clamped in a top portion (21) of the femur (11). The femoral head (12) is a distinct and removable component with respect to the pin means (18) and the pin means (18) are provided with, or are associated with, coupling means (15) which are inserted into a mating seating (14) of the femoral head (12) in order to obtain a removable constraint between the latter and the pin means (18).

M. DRAWING

International Class: A61F 02/36

Description of the invention entitled:

"FEMORAL PROSTHESIS FOR HIP ARTICULATION"

in the name of LIMA LTO SpA, an Italian Company with
5 offices in Via Nazionale, 36 - 33030 VILLANOVA DI S.
DANIELE DEL FRIULI (UD)

filed on

under n.

FIELD OF THE INVENTION

10 The present invention concerns a femoral prosthesis
for the hip articulation, of the so-called "resurfacing"
type, that is, a prosthesis suitable to be fixed on the top
of a neck of the femur, leaving it substantially intact.
The femoral prosthesis according to the invention comprises
15 a head, substantially hemispherical in shape, able to be
inserted into a corresponding acetabular seating of the
hip, and a pin element able to be clamped in the upper part
of the femur.

The femoral prosthesis according to the present
20 invention is of the at least partly interchangeable type
due to the fact that the pin element is a distinct element
and does not form a single piece with the femoral head. In
this way, for example, the femoral head can be replaced by
another, new one of the same type or by others of a
25 different shape and /or size, even during the pre-
installation step, for example to obtain a different
orientation of the femoral head with respect to the pin
element.

With the femoral prosthesis according to the present
30 invention it is also possible to vary the reciprocal
distance of the head with respect to the pin element, in
order to modify for example the tension exerted by the head
itself along the whole femur. Moreover, the prosthesis

according to the present invention allows to perform the implant in two distinct steps, at a first moment inserting the pin element into the femur along the cephalic axis, and at a second moment, after having made a relative seating on the natural femoral head, applying the head.

BACKGROUND OF THE INVENTION

A femoral prosthesis is known, the so-called resurfacing prosthesis, for the articulation of a femur in a hip, which comprises as its essential parts a metal pin, straight or arched, which is inserted and fixed in the neck of the femur, and a femoral head, made in a single piece with the pin and able to be inserted into a mating acetabular cup, previously inserted into a natural acetabular seating.

This type of prosthesis is called a resurfacing prosthesis precisely because it provides to replace only part of the femoral head, leaving the neck of the femur intact. This prosthesis, with respect to the complete prosthesis, has the advantage that it causes minimum anatomical alteration; this allows to preserve the bone tissues in favour of possible subsequent revision interventions, which can thus be carried out as if it were a normal first implant.

To use such resurfacing prostheses it is necessary that the patient should have a good quality bone tissue and minimum anatomical alteration of the femoral head.

Moreover, the diameter of the artificial femoral head must be approximately the same value as the natural head, in order to keep unchanged the anatomy of the proximal part of the femur. Since the acetabular cup wherein the head is inserted must have a high inner diameter, the acetabular cup must necessarily have a very limited thickness. Therefore, for reasons of structural resistance, in the

present state of the art it is preferred not to use cups made of polyethylene, or of ceramic, which require an adequately large thickness; therefore, the whole prosthetic implant is preferably made completely of metal material, achieving a coupling through metal-metal sliding.

The metal used is preferably cobalt, or a cobalt-based alloy, because of its good resistance to the wear caused by the coupling.

A first disadvantage of resurfacing femoral prostheses of a known type is the fact that cobalt-based alloys can be integrated with the bone tissue only with difficulty; there is therefore the risk that the pin is not adequately fixed in the femur and this can create damage to the bone structure, or at least can cause its stabilizing function to be reduced.

Another disadvantage concerns the surgical technique currently adopted to apply the resurfacing femoral prosthesis of a known type. The classical surgical technique provides to prepare an outer cylindrical/conical seating made by milling the anatomical femoral head and to insert the pin into the diaphysis channel. The milling and subsequent application of the femoral head are then carried out in absence of a point of reference on the femur and, consequently, there is the possible risk of introducing the pin in an incorrect position.

Applicant has devised and embodied the present invention to overcome these shortcomings of the state of the art and to obtain other advantages.

SUMMARY OF THE INVENTION

The present invention is set forth and characterized in the main claims, while the dependent claims describe other characteristics of the invention.

The purpose of the present invention is to obtain a

femoral prosthesis of the so-called resurfacing type by means of which it is possible to selectively combine various types of prosthetic heads to a same pin, in order to optimize, on each occasion, the configuration of the prosthetic implant with regard to the real conditions of the articulation.

Another purpose of the invention is to achieve a femoral prosthesis whose head can be easily replaced without intervening on the pin attached to the end of the femur.

A further purpose is to facilitate the surgeon's work, allowing him both to have a precise reference during the installation of the head, and also to implant the prosthesis in two different steps, even distant over time.

In accordance with these purposes, in a femoral prosthesis of a hip of the so-called resurfacing type, which comprises at least a femoral head of a hemispherical shape and relative pin means, able to be engaged and clamped in a top portion of the femur, the femoral head is a distinct and removable component with respect to the pin means. According to a characteristic of the present invention, in fact, the pin means are provided with, or are associated with, coupling means able to be inserted into a mating seating of the femoral head in order to obtain a removable constraint between the latter and the pin means.

In this way, the femoral head can be removed from the acetabular seating without operating directly on the bone, and therefore with great ease.

In one embodiment of the present invention, the coupling means comprise a flange-type insert able to be connected to the pin means, which is inserted and coupled in a mating cavity made in the femoral head.

In a preferential embodiment of the invention, the

constraint between the flange-type insert and the femoral head is achieved by means of conical coupling. According to this embodiment, the flange-type insert is at least partly hollow inside and defines an inner seating for attachment
5 to the top portion made on the femur.

According to a variant, the flange-type insert is able to be simply rested on the top portion of the femur suitably prepared.

After having inserted the pin means in the top of the
10 femur, the flange-type insert can be attached, for example hooked, cemented, or rested on the femoral seating and, at a second moment, the femoral head is anchored on said flange-type insert, for example by means of the aforesaid conical coupling. The invention allows to carry out, with
15 the same flange-type insert already attached to the femoral seating, a plurality of trials with various femoral heads, in order to vary the head/pin distance and orientation of the prosthetic implant.

Another advantage of the present invention is that it
20 allows to use femoral prostheses wherein the femoral head is made of a different material from the pin means.

Thanks to this, the pin means and the coupling means can be made with a material, for example titanium or titanium alloy, particularly suitable for integration in a
25 bone tissue, while the femoral head can be made of an anti-wear material, such as for example cobalt alloy, as in resurfacing femoral prostheses of a known type, or of ceramic material of a suitable and high resistance.

BRIEF DESCRIPTION OF THE DRAWINGS

30 These and other characteristics of the present invention will become apparent from the following description of a preferential form of embodiment, given as a non-restrictive example, with reference to the attached

drawings wherein:

- fig. 1 shows a section view of the femoral prosthesis according to the invention assembled and fixed in an acetabular seating;
- 5 - fig. 2 shows an exploded view of the prosthesis in fig. 1.

DETAILED DESCRIPTION OF A PREFERENTIAL FORM OF EMBODIMENT
OF THE INVENTION

With reference to the attached drawings, a resurfacing
10 femoral prosthesis 10 according to the present invention is attached to the top 21 of a natural femoral head and is able to replace the natural femoral head, leaving the neck of the femur 11 substantially intact.

The femoral prosthesis 10 comprises a head or cap 12,
15 substantially hemispherical in shape, in the inner zone of which a cavity 14 is made, and a pin 18, in this case with an arched shape, which is inserted under pressure at the base of the top 21 of the natural femoral head.

In one embodiment of the invention, the pin 18,
20 whether it be straight or arched, has a transverse section which is not constant over its whole length, but conical, with a greater section in correspondence with an upper end 22a towards the head 12 and smaller at the opposite end 22b, which is inserted into the neck of the femur 11. This
25 shape of the pin 18 allows to facilitate, during the surgical operation, the insertion under pressure from above.

The head 12 is able to be inserted into an acetabular cup 23 which is fixed to a mating acetabular seating 13 of
30 a hip 19.

The femoral prosthesis 10 according to the present invention is of the interchangeable type, due to the fact that the head 12 and the pin 18 are two distinct elements.

According to one characteristic of the present invention, a flange-type insert 15 is interposed between the head 12 and the pin 18 and is able to be inserted into the cavity 14 of the head 12 to allow a correct positioning and coupling of the two elements.

The flange-type insert 15 comprises an upper coupling portion 15a, hollow inside, in which a seating 17 is made inside which the upper end 22 of the pin 18, protruding from the top 21, is inserted along a cephalic axis X and coupled through conical coupling.

The flange-type insert 15 also comprises a lower portion 15b, also hollow inside, which is able to be mounted, due to coupling in shape with its inner perimeter, on the top 12.

The lower portion 15b, which is substantially conical in shape, is able to be inserted, by means of another conical coupling with its outer perimeter, into the cavity 14 of the head 12.

The top 21 of the natural femoral head, after being sectioned to obtain a plane surface 30 and substantially orthogonal to the cephalic axis X, is suitably milled, before the flange-type insert 15 is mounted, until an outer seating is obtained of a conical or cylindrical shape, into which said insert 15 is inserted.

According to a variant, the top 21 is not milled and the flange-type insert 15 is simply rested flat on the resection of the natural femoral head.

Above the upper coupling portion 15a there is also a housing seating 25 for an attachment screw 26, able to clamp the flange-type insert 15 with the pin 18 in the assembled condition. The flange-type insert 15 can also be cemented on the top 21.

According to one characteristic of the invention, the

distance between the pin 18 and the head 12 can be selectively varied using a flange element 15 of different size. To be more exact, by varying the size of the coupling portion 15a with respect to the size of the lower portion 15b it is possible to obtain a variation in the distance of the head 12 from the neck of the femur 11 so as to vary, also during the step when the implant is tested, the articular tension and the offset with respect to a diaphysis axis Y of the neck of the femur 11.

10 By means of the femoral prosthesis 10 as described heretofore, it is also possible to modulate, with a large number of combinations, the diameter of the head 12 and the pin 18, according to the size of the neck of the femur 11 and of the acetabular seating 13, in order to obtain a
15 prosthesis suitable to the structure and conformation of the natural femur, even in the case of a worsening of the articulation.

A pre-defined angle of the conical coupling between the flange-type insert 15 and the pin 18, with respect to
20 the other conical coupling between the head 12 and the flange-type insert 15, allows to choose, with a large number of possible combinations and according to necessity, the reciprocal orientation of the three elements.

To this end, according to a first embodiment of the
25 invention, the flange-type insert 15 can be designed in such a way that the axis of the cone of one coupling is centered with a particular angle with respect to the axis of the cone of the other coupling.

This allows the head 12, at the moment of coupling of
30 the flange-type insert 15 and the head 12, to be already automatically oriented with a certain angle with respect to the pin 18 and hence to the neck of the femur 11.

In another embodiment, the axis of the cone of one

coupling is in an eccentric position with respect to the axis of the cone of the other coupling.

This allows both to automatically orientate the head 12 with respect to the pin 18 and also to translate the head 12, displacing its center in a front-rear or side-
5 median direction with respect to the neck of the femur 11.

The type of coupling between the elements is not in any case restrictive in the field of the present invention.

In a first variant, not shown in the drawings, the
10 head 12 can be hooked to the flange-type insert 15, or screwed.

According to another embodiment, the flange-type insert 15 is constrained fixedly to the pin 18. In accordance with this embodiment, the flange-type insert 15
15 is made in a single piece with the pin 18.

In another embodiment, the flange-type insert 15 is cemented on the pin 18.

According to another characteristic of the invention, the head 12 is made of a different material with respect to
20 the pin 18 and the flange-type insert 15.

To be more exact, the pin 18 and the flange-type insert 15 are advantageously made of titanium or a titanium alloy, since this metal is suitable for bone integration, whereas the head 12 is advantageously made of a cobalt-
25 based alloy or other material with a great mechanical resistance.

The implant of the femoral prosthesis 10 is achieved in the following manner.

At a first moment, a resection is made of the top 21
30 in order to obtain the plane surface 30 substantially orthogonal to the cephalic axis X.

According to a variant, the resection of the top 21 is not perpendicular to the cephalic axis X of the neck of the

femur 11, but is inclined by a certain angle with the purpose of increasing the compression forces on the femur and of reducing the shearing forces of the resection.

At a second moment, the pin 18 is inserted, approximately on the equatorial level, passing through the top portion 21 of the neck of the femur 11 letting its upper end 22a emerge.

Once fixed, the pin 18 can function as a guide for milling and preparing the top 21 on which the flange-type insert 15 is mounted. The milled portion is shown in fig. 2 by a line of dashes.

Subsequently, the flange-type insert 15 is mounted on the top 21, coupled and clamped to the upper end 22a of the pin 18 by means of the screw 26.

When the flange-type insert 15 is mounted, the head 12 is coupled thereon.

The femoral prosthesis 10 also allows to implant the prosthesis in two distinct steps, even distant over time, as in the case of the so-called two-time prosthesis application.

Two-time prosthesis application is particularly useful in the event that it is necessary to momentarily support the bone of a femur in a first step, transferring healthy bone tissue inside the femur, by means of lateral access, which is done under the greater trochanter. The transfer of bone tissue is carried out for example in interventions to fill a natural femoral head in the case of avascular necrosis thereof.

The pin 18 is introduced in this case not from the top 21, but through the lateral access and is positioned along the cephalic axis X, in such a way that the upper end 22a remains inside the natural femoral head in order to consolidate the healthy bone tissue.

Once the pin 18 has been integrated into the bone, should it be necessary to prosthetize the articulation of the hip, it is sufficient to section the upper portion of the femur, as described above, to couple the flange-type
5 insert 15 and the head 12.

It is clear that modifications or additions may be made to the femoral prosthesis 10 as described heretofore, without departing from the field of protection of the present invention.

10 It is also clear that, although the description refers to a specific example, a skilled person shall be able to achieve other equivalent forms of femoral prosthesis 10, all of which shall come within the field of the present invention.

CLAIMS

1. Femoral prosthesis of a hip able to allow the articulation of a femur (11) in a corresponding acetabular seating (13) and comprising at least a femoral head (12) of
5 a hemispherical shape able to be inserted into said acetabular seating (13), and pin means (18) able to be engaged and clamped in a top portion (21) of the femur (11), characterized in that said femoral head (12) is a distinct and removable component with respect to said pin
10 means (18) and that said pin means (18) are provided with, or are associated with, coupling means (15) able to be inserted into a mating seating (14) of said femoral head (12) in order to obtain a removable constraint between said femoral head (12) and said pin means (18).
- 15 2. Femoral prosthesis as in claim 1, characterized in that said coupling means comprise a flange-type insert (15).
3. Femoral prosthesis as in claim 2, characterized in that said flange-type insert (15) is connected to said pin means (18) and is able to be coupled and inserted in said mating
20 seating (14).
4. Femoral prosthesis as in claim 2 or 3, characterized in that said flange-type insert (15) comprises a first portion (15b) able to be coupled by means of a first coupling in said mating seating (14) made in said femoral head (12).
- 25 5. Femoral prosthesis as in claim 4, characterized in that said first coupling is of the conical type.
6. Femoral prosthesis as in claim 4 or 5, characterized in that said first portion (15b) is hollow inside and defines a relative seating for the attachment of said top portion
30 (21).
7. Femoral prosthesis as in claim 2, characterized in that said flange-type insert (15) is able to be rested on said top portion (21).

8. Femoral prosthesis as in any claim hereinbefore, characterized in that said coupling means (15) are removable with respect to said pin means (18).

9. Femoral prosthesis as in claims 2 and 8, characterized in that said flange-type insert (15) comprises a second portion (15a), in which a seating (17) is made, able to allow a second coupling of said flange-type insert (15) with an upper end (22a) of said pin means (18).

10. Femoral prosthesis as in claim 9, characterized in that said second coupling is of the conical type.

11. Femoral prosthesis as in claim 9 or 10, characterized in that in the upper zone of said second portion (15a) there is a housing seating (25) for an attachment screw (26) able to clamp said flange-type insert (15) in an assembled condition with said pin means (18).

12. Femoral prosthesis as in any claim from 2 to 11 inclusive, characterized in that said flange-type insert (15) has different eccentric couplings with said femoral head (12).

13. Femoral prosthesis as in claims 5 and 10, characterized in that the axis of the cone of said first coupling is centered, or is eccentric, with respect to the cone of said second conical coupling.

14. Femoral prosthesis as in any claim from 2 to 13 inclusive, characterized in that said flange-type insert (15) is able to be cemented on said top portion (21).

15. Femoral prosthesis as in claim 1, characterized in that said coupling means are made in a single piece with said pin means (18).

16. Femoral prosthesis as in any claim hereinbefore, characterized in that said femoral head (12) is made of a different anti-wear material with respect to said pin means (18), which are made of a material able to be easily

integrated with a bone tissue.

17. Femoral prosthesis as in any claim from 2 to 16 inclusive, characterized in that said pin means (18) and said flange-type insert (15) are made of titanium or
5 titanium alloy, whereas said femoral head (12) is made of a cobalt alloy, or other material with high mechanical resistance.

18. Femoral prosthesis as in any claim hereinbefore, characterized in that said pin means (18) are substantially
10 conical in shape, with a lesser section at a first end (22b) on the side where it is inserted in said top portion (21), and a greater section at a second end (22a) towards said coupling means (15).

19. Method to implant a femoral prosthesis as in any one of
15 the previous claims, characterized in that in a first step a pin (18) is inserted from the top (21) of the neck of a femur (11) letting an upper end thereof (22a) emerge, then a flange-type insert (15) is coupled and clamped to said upper end (22a) and finally a femoral head (12) is coupled
20 and clamped to said flange-type insert (15).

20. Femoral prosthesis for hip articulation and relative implantation method substantially as described with reference to the attached drawings.

for LIMA LTO SpA - mm/sl